LG-4878 REV 9/89

Contains No CBI

DU PONT

92 OCT 27 PM 2:20

LEGAL
Wilmington, Delaware 19898

21
8EHQ-92-12223

(A)

No CBI 88920010445

INIT

Certified Mail
Return Receipt Requested

October 15, 1992

Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street., S.W.
Washington, D.C. 20460
Attn: Section 8(e) Coordinator (CAP Agreement)

Dear Coordinator:

8ECAP-0025

On behalf of the Regulatee and pursuant to Unit II B.1.b. and Unit II C of the 6/28/91CAP Agreement, E.I. Du Pont de Nemours and Co. hereby submits (*in triplicate*) the attached studies. Submission of this information is voluntary and is occasioned by unilateral changes in EPA's standard as to what EPA now considers as reportable information. Regulatee's submission of information is made solely in response to the new EPA §8(e) reporting standards and is not an admission: (1) of TSCA violation or liability; (2) that Regulatee's activities with the study compounds reasonably support a conclusion of substantial health or environmental risk or (3) that the studies themselves reasonably support a conclusion of substantial health or environmental risk.

The "Reporting Guide" creates new TSCA 8(e) reporting criteria which were not previously announced by EPA in its 1978 Statement of Interpretation and Enforcement Policy, 43 Fed Reg 11110 (March 16, 1978). The "Reporting Guide states criteria which expands upon and conflicts with the 1978 Statement of Interpretation. Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" raises significant due processes issues and clouds the appropriate reporting standard by which regulated persons can assure TSCA Section 8(e) compliance.

For Regulatee,

Mark H. Christman
Counsel
Legal D-7158
1007 Market Street
Wilmington, DE 19898
(302) 774-6443

mm
3/6/95

ATTACHMENT 1

Submission of information is made under the 6/28/91 CAP Agreement, Unit II. This submission is made voluntarily and is occasioned by recent changes in EPA's TSCA §8(e) reporting standard; such changes made, for the first time in 1991 and 1992 without prior notice and in violation of Regulatee's constitutional due process rights. Regulatee's submission of information under this changed standard is not a waiver of its due process rights; an admission of TSCA violation or liability, or an admission that Regulatee's activities with the study compounds reasonably support a conclusion of substantial risk to health or to the environment. Regulatee has historically relied in good faith upon the 1978 Statement of Interpretation and Enforcement Policy criteria for determining whether study information is reportable under TSCA §8(e), 43 Fed Reg 11110 (March 16, 1978). EPA has not, to date, amended this Statement of Interpretation.

After CAP registration, EPA provided the Regulatee the June 1, 1991 "TSCA Section 8(e) Reporting Guide". This "Guide" has been further amended by EPA, EPA letter, April 10, 1992. EPA has not indicated that the "Reporting Guide" or the April 1992 amendment supersedes the 1978 Statement of Interpretation. The "Reporting Guide" and April 1992 amendment substantively lowers the Statement of Interpretation 's TSCA §8(e) reporting standard[2]. This is particularly troublesome as the "Reporting Guide" states criteria, applied retroactively, which expands upon and conflicts with the Statement of Interpretation.[3] Absent amendment of the Statement of Interpretation, the informal issuance of the "Reporting Guide" and the April 1992 amendment clouds the appropriate standard by which regulated persons must assess information for purposes of TSCA §8(e).

---

[2]In sharp contrast to the Agency's 1977 and 1978 actions to soliciting public comment on the proposed and final §8(e) Policy, EPA has unilaterally pronounced §8(e) substantive reporting criteria in the 1991 Section 8(e) Guide without public notice and comment, See 42 Fed Reg 45362 (9/9/77), "Notification of Substantial Risk under Section 8(e): Proposed Guidance".

[3]A comparison of the 1978 Statement of Interpretation and the 1992 "Reporting Guide" is a appended.

Throughout the CAP, EPA has mischaracterized the 1991 guidance as reflecting "longstanding" EPA policy concerning the standards by which toxicity information should be reviewed for purposes of §8(e) compliance. Regulatee recognizes that experience with the 1978 Statement of Interpretation may cause a review of its criteri. Regulatee supports and has no objection to the Agency's amending reporting criteria *provided that* such amendment is not applied to the regulated community in an unfair way. However, with the unilateral announcement of the CAP under the auspices of an OCM enforcement proceeding, EPA has wrought a terrific unfairness since much of the criteria EPA has espoused in the June 1991 Reporting Guide and in the Agency's April 2, 1992 amendment is new criteria which does not.exist in the 1978 Statement of Interpretation and Enforcement Policy.

The following examples of new criteria contained in the "Reporting Guide" that is not contained in the Statement of Interpretation follow:

- o even though EPA expressly disclaims each "status report" as being preliminary evaluations that should not be regarded as final EPA policy or intent[4], the "Reporting Guide" gives the "status reports" great weight as "sound and adequate basis" from which to determine mandatory reporting obligations. ("Guide" at page 20).
- o the "Reporting Guide" contains a matrix that establishes new numerical reporting "cutoff" concentrations for acute lethality information ("Guide" at p. 31). Neither this matrix nor the cutoff values therein are contained in the Statement of Interpretation. The regulated community was not made aware of these cutoff values prior to issuance of the "Reporting Guide" in June, 1991.
- othe "Reporting Guide" states new specific definitional criteria with which the Agency, for the first time, defines as 'distinguishable neurotoxicological effects'; such criteria/guidance not expressed in the 1978 Statement of Interpretation.[5];

- othe "Reporting Guide" provides new review/ reporting criteria for irritation and sensitization studies; such criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy.
- othe "Reporting Guide" publicizes certain EPA Q/A criteria issued to the Monsanto Co. in 1989 which are not in the Statement of Interpretation; have never been published in the Federal Register or distributed by the EPA to the Regulatee. Such Q/A establishes new reporting criteria not previously found in the 1978 Statement of Interpretation/Enforcement Policy .

---

[4]The 'status reports' address the significance, if any, of particular information reported to the Agency, rather than stating EPA's interpretation of §8(e) reporting criteria. In the infrequent instances in which the status reports contain discussion of reportability, the analysis is invariably quite limited, without substantial supporting scientific or legal rationale.

[5] *See, e.g,* 10/2/91 letter from Du Pont to EPA regarding the definition of 'serious and prolonged effects' as this term may relate to transient anesthetic effects observed at lethal levels; 10/1/91 letter from the American Petroleum Institute to EPA regarding clarification of the Reporting Guide criteria.

In discharging its responsibilities, an administrative agency must give the regulated community fair and adequate warning to as what constitutes noncompliance for which penalties may be assessed.

> Among the myriad applications of the due process clause is the fundamental principle that statutes and regulations which purport to govern conduct must give an adequate warning of what they command or forbid.... Even a regulation which governs purely economic or commercial activities, if its violation can engender penalties, must be so framed as to provide a constitutionally adequate warning to those whose activities are governed.

Diebold, Inc. v. Marshall, 585 F.2d 1327, 1335-36 (D.C. Cir. 1978). *See also*, Rollins Environemntal Services (NJ) Inc. v. U.S. Environmental Protection Agency, 937 F. 2d 649 (D.C. Cir. 1991).

While neither the are rules, This principle has been applied to hold that agency 'clarification', such as the Statement of Interpretation, the "Reporting Guide" nor the April 1992 amendments will not applied retroactively.

> ...a federal court will not retroactively apply an unforeseeable interpretation of an administrative regulation to the detriment of a regulated party on the theory that the post hoc interpretation asserted by the Agency is generally consistent with the policies underlying the Agency's regulatory program, when the semantic meaning of the regulations, as previously drafted and construed by the appropriate agency, does not support the interpretation which that agency urges upon the court.

Standard Oil Co. v. Federal Energy Administration, 453 F. Supp. 203, 240 (N.D. Ohio 1978), aff'd sub nom. Standard Oil Co. v. Department of Energy, 596 F.2d 1029 (Em. App. 1978):

The 1978 Statement of Interpretation does not provide adequate notice of, and indeed conflicts with, the Agency's current position at §8(e) requires reporting of all 'positive' toxicological findings without regard to an assessment of their relevance to human health. In accordance with the statute, EPA's 1978 Statement of Interpretation requires the regulated community to use scientific judgment to evaluate the significance of toxicological findings and to determining whether they reasonably support a conclusion of a substantial risk. Part V of the Statement of Interpretation urges persons to consider "the fact or probability" of an effect's occurrence. Similarly, the 1978 Statement of Interpretation stresses that an animal study is reportable only when "it contains reliable evidence ascribing the effect to the chemical." 43 Fed Reg. at 11112. Moreover, EPA's Statement of Interpretation defines the substantiality of risk as a function of both the seriousness of the effect and the probability of its occurrence. 43 Fed Reg 11110 (1978). Earlier Agency interpretation also emphasized the "substantial" nature of a §8(e) determination. See 42 Fed Reg 45362, 45363

(1977). [Section 8(e) findings require "extraordinary exposure to a chemical substance...which critically imperil human health or the environment"].

The recently issued "Reporting Guide" and April 1992 Amendment guidance requires reporting beyond and inconsistent with that required by the Statement of Interpretation. Given the statute and the Statement of Interpretation's explicit focus on substantial human or environmental risk, whether a substance poses a "substantial risk" of injury requires the application of scientific judgment to the available data on a case-by-case basis.

If an overall weight-of-evidence analysis indicates that this classification is unwarranted, reporting should be unnecessary under §8(e) because the available data will not "reasonably support the conclusion" that the chemical presents a substantial risk of serious adverse consequences to human health.

Neither the legislative history of §8(e) nor the plain meaning of the statute support EPA's recent lowering of the reporting threshold that TSCA §8(e) was intended to be a sweeping information gathering mechanism. In introducing the new version of the toxic substances legislation, Representative Eckhart included for the record discussion of the specific changes from the version of H. R. 10318 reported by the Consumer Protection and Finance Subcommittee in December 1975. One of these changes was to modify the standard for reporting under §8(e). The standard in the House version was changed from "causes or contributes to an unreasonable risk" to "causes or significantly contributes to a substantial risk". This particular change was one of several made in TSCA §8 to avoid placing an undue burden on the regulated community. The final changes to focus the scope of Section 8(e) were made in the version reported by the Conference Committee.

The word "substantial" means "considerable in importance, value, degree, amount or extent". Therefore, as generally understood, a "substantial risk" is one which will affect a considerable number of people or portion of the environment, will cause serious injury and is based on reasonably sound scientific analysis or data. Support for the interpretation can be found in a similar provision in the Consumer Product Safety Act. Section 15 of the CPSA defines a "substantial product hazard" to be:

> "a product defect which because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise, creates a substantial risk of injury to the public."

Similarly, EPA has interpreted the word 'substantial' as a quantitative measurement. Thus, a 'substantial risk' is a risk that can be quantified, *See,* 56 Fed Reg 32292, 32297 (7/15/91). Finally, since information pertinent to the exposure of humans or the environment to chemical substances or mixtures may be obtained by EPA through Sections 8(a) and 8(d) regardless of the degree of potential risk, §8(e) has specialized function. Consequently, information subject to §8(e) reporting should be of a type which would lead a reasonable man to conclude that some type action was required immediately to prevent injury to health or the environment.

Attachment

Comparison:

Reporting triggers found in the 1978 "Statement of Interpretation/ Enforcement Policy",43 Fed Reg 11110 (3/16/78) and the June 1991 *Section 8(e) Guide.*

TEST TYPE	1978 POLICY CRITERIA EXIST?	New 1991 GUIDE CRITERIA EXIST?
ACUTE LETHALITY		
Oral	N}	Y}
Dermal	N}	Y}
Inhalation (Vapors)	}[6]	}[7]
aerosol	N}	Y}
dusts/ particles	N}	Y}
SKIN IRRITATION	N	Y[8]
SKIN SENSITIZATION (ANIMALS)	N	Y[9]
EYE IRRITATION	N	Y[10]
SUBCHRONIC (ORAL/DERMAL/INHALATION)	N	Y[11]
REPRODUCTION STUDY	N	Y[12]
DEVELOPMENTAL TOX	Y[13]	Y[14]

---

[6] 43 Fed Reg at 11114, comment 14:
"This policy statements directs the reporitng of specifiec effects when unknown to the Administrator. Many routine tests are based on a knowledge of toxicity associated with a chemicalL unknown effects occurring during such a range test may have to be reported if they are those of concern tot he Agency and if the information meets the criteria set forth in Parts V and VII."

[7] Guide at pp.22, 29-31.

[8] Guide at pp-34-36.

[9] Guide at pp-34-36.

[10] Guide at pp-34-36.

[11] Guide at pp-22; 36-37.

[12] Guide at pp-22

[13] 43 Fed Reg at 11112
"Birth Defects" listed.

[14] Guide at pp-22

NEUROTOXICITY	N	Y[15]
CARCINOGENICITY	Y[16]	Y[17]
MUTAGENICITY		
In Vitro	Y}[18]	Y} [19]
In Vivo	Y}	Y}
ENVIRONMENTAL		
Bioaccumulation	Y}	N
Bioconcentration	Y}[20]	N
Oct/water Part. Coeff.	Y}	N
Acute Fish	N	N
Acute Daphnia	N	N
Subchronic Fish	N	N
Subchronic Daphnia	N	N
Chronic Fish	N	N
AVIAN		
Acute	N	N
Reproductive	N	N
Reprodcutive	N	N

---

[15] Guide at pp-23; 33-34.

[16] 43 Fed Reg at 11112
"Cancer" listed

[17] Guide at pp-21.

[18] 43 Fed Reg at 11112; 11115 at Comment 15
"Mutagenicity" listed/ *in vivo* vs *invitro* discussed; discussion of "Ames test".

[19] Guide at pp-23.

[20] 43 Fed Reg at 11112; 11115 at Comment 16.

CAS# 79-11-8
Chem: Monochloroacetic acid
Title: Letter
Date: 7/30/69
Summary of Effects: Repeat of human death report

HERCULES INCORPORATED

July 30, 1969

To: Members of Occupational Health Committee - MCA

From: E. E. Christofano

This letter will make available to you some important new information on the hazards to humans from skin contact with monochloroacetic acid.

We recently experienced an accident in which an employe was exposed over an estimated 10% of his skin surface to warm liquid monochloroacetic acid. Prompt (estimated at less than a minute) and thorough washing with water for about an hour apparently removed the soluble salt. Skin burns, except for a small area, were considered first degree. While under observation at the plant dispensary, the victim's condition suddenly worsened and death occurred 10 hours post exposure in the local hospital despite vigorous medical therapy.

While monochloroacetic acid is known to be corrosive to the skin, this fatality was unexpected on the basis of facts available at the time. Subsequent animal toxicity experiments have demonstrated that fatalities would be expected among rabbits when only 3% of the skin area was exposed. Furthermore, thorough washing of the skin area after one minute of exposure failed to materially reduce the incidence of mortality or the extent of skin destruction.

Additional studies are being conducted to develop suitable treatment methods. Until this information is available, we recommend great care to avoid skin contact.

Case History:

A 24-year old colored ex-serviceman, who weighed about 240 pounds, climbed on the rims of closely stored open cardboard drums that contained molten (580 C.) monochloroacetic acid. The worker slipped and his leg fell into one of the containers which tipped over and spilled acid on his other leg. According to the victim he immediately hurried back across the top of the drums, remo[illegible] his pants, called for help and went under an emergency shower within approximately 30 seconds. His co-workers immediately came [illegible] and removed his socks and shoes. Since the shower water was cold they had him place his legs in two drums of running water. Washing continued for [illegible] to 15 minutes until he was taken to the First Aid Room by car. The plant physician washed his legs in a foot bath where they were flushed with running water for 45 minutes. During this time he vomited twice having eaten shortly before the accident. He remained alert and did not complain of pain but mentioned numbness in the calf of his

left leg. During the next hour he had spells of vomiting interspersed with napping but responded when spoken to. Three hours after the injury his respiratory rate had increased to 30 and his pulse to 104. There was some irregularity of the heart rate although the volume was good.

While being transferred to the hospital he began a convulsive seizure and had to be restrained. Shortly after admission he went into deep shock with no palpable pulse or blood pressure. His respiratory rate was increased and there was wheezing with some rales at the bases. He was given intravenous glucose and saline with 80 mg. of solu-medrol (Cortisone) in the first two hours and 20 mg. later. Antihistamines were administered intramuscularly. He responded rather quickly with a return of his blood pressure to 110 but he did not regain consciousness. The blood studies showed a hemoglobin of 15.9 gm, white blood count of 25,200 and hematocrit 46. The CO_2, sodium, and chloride were normal; potassium was low and he was given intravenous KCl. An electrocardiogram was within normal limits. He never did regain consciousness and died 7 hours after hospitalization (11 hours after the injury).

The autopsy showed congestion, hemorrhage and confluent petechia of the heart, lungs and thymus, congestion of the liver, a persistent thymus, and massive bilateral pulmonary congestion and edema.

The burns which involved both legs to just above the knee were mostly first degree with some second degree patches.

Animal Studies:

The attached table summarizes the results to date on studies to investigate the skin toxicity of monochloroacetic acid with rabbits.

With 15-minute exposure, when as little as 3% of the skin surface was treated with MCA, two out of two rabbits died. When 1% of the skin surface was treated for 15 minutes, no deaths occurred.

With one-minute exposure, followed by exhaustive washing with water, when 10% of the skin surface was treated, two out of two rabbits died. When 5% of the surface was treated, one out of two rabbits died. No deaths occurred with 3% surface exposure.

Washing of the skin with sodium bicarbonate after one-minute exposure and application of sodium bicarbonate paste to the treated area showed no difference in mortality from washing with water, although the severity of the skin lesion appeared slightly less.

Deaths occur in two to five hours, with animals showing remarkably few symptoms. The animals become lethargic and comatose before death. On autopsy, the peripheral venous system is distended and the right ventricle of the heart appears almost devoid of blood. Microscopic examination of the organs has not been completed.

CULES

We are currently designing an experiment to investigate the physiologic cause of death, so that some logical course of treatment can be adopted for exposure to MCA. Until some effective treatment procedure can be developed, and because of the speed of MCA absorption through the skin, it is obvious that any significant skin exposure to MCA should be avoided.

Having brought this to your attention we now request your comments or suggestions on treatment procedures which could be used if this kind of accident recurred. Hopefully the Manufacturing Chemists Association (MCA) can assist in the handling of monochloroacetic acid (MCA).

EEC:abp
attach.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

Mark H. Christman
Counsel
E. I. Du Pont De Nemours and Company
Legal D-7010-1
1007 Market Street
Wilmington, Delaware 19898

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 18 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure 12223A

Triage of 8(e) Submissions

Date sent to triage: APR 20 1995 NON-CAP (CAP)

Submission number: 12223A TSCA Inventory: (Y) N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

(ATOX) SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX ~~EPI~~ RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document (1) 2 **pages** 1 1st TAB **pages** 1, TABS

Notes:

Contractor reviewer : PJL **Date:** 4/3/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ-1092-12223 SEQ. A

TYPE: (INT) SUPP FLWP

SUBMITTER NAME: E. I. Dupont de Nemours and Company

SUB. DATE: 10/15/92 OTS DATE: 10/27/92 CSRAD DATE: 03/06/95

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
(0678) CAP NOTICE

VOLUNTARY ACTIONS:
0401 NO ACTION REPORTED
(0402) STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKERS/OTHERS
0404 LABEL/MSDS CHANGES
(0405) PROCESS/HANDLING CHANGES
0406 APP/USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

CHEMICAL NAME:

CAS#
79-11-8

INFORMATION TYPE:		P	F	C
0201	ONCO (HUMAN)	01	02	04
0202	ONCO (ANIMAL)	01	02	04
0203	CELL TRANS (IN VITRO)	01	02	04
0204	MUTA (IN VITRO)	01	02	04
0205	MUTA (IN VIVO)	01	02	04
0206	REPRO/TERATO (HUMAN)	01	02	04
0207	REPRO/TERATO (ANIMAL)	01	02	04
0208	NEURO (HUMAN)	01	02	04
0209	NEURO (ANIMAL)	01	02	04
0210	ACUTE TOX. (HUMAN)	01	02	04
0211	CHR. TOX. (HUMAN)	01	02	04
(0212)	ACUTE TOX. (ANIMAL)	01	02	04
0213	SUB ACUTE TOX (ANIMAL)	01	02	04
0214	SUB CHRONIC TOX (ANIMAL)	01	02	04
0215	CHRONIC TOX (ANIMAL)	01	02	04

INFORMATION TYPE:		P	F	C
0216	EPI/CLIN	01	02	04
0217	HUMAN EXPOS (PROD CONTAM)	01	02	04
(0218)	HUMAN EXPOS (ACCIDENTAL)	01	02	04
0219	HUMAN EXPOS (MONITORING)	01	02	04
0220	ECO/AQUA TOX	01	02	04
0221	ENV. OCCC/REL/FATE	01	02	04
0222	EMER INCI OF ENV CONTAM	01	02	04
0223	RESPONSE REQEST DELAY	01	02	04
0224	PROD/COMP/CHEM ID	01	02	04
0225	REPORTING RATIONALE	01	02	04
0226	CONFIDENTIAL	01	02	04
0227	ALLERG (HUMAN)	01	02	04
0228	ALLERG (ANIMAL)	01	02	04
0239	METAB/PHARMACO (ANIMAL)	01	02	04
0240	METAB/PHARMACO (HUMAN)	01	02	04

INFORMATION TYPE:		P	F	C
0241	IMMUNO (ANIMAL)	01	02	04
0242	IMMUNO (HUMAN)	01	02	04
0243	CHEM/PHYS PROP	01	02	04
0244	CLASTO (IN VITRO)	01	02	04
0245	CLASTO (ANIMAL)	01	02	04
0246	CLASTO (HUMAN)	01	02	04
0247	DNA DAM/REPAIR	01	02	04
0248	PROD/USE/PROC	01	02	04
0251	MSDS	01	02	04
0299	OTHER	01	02	04

Atox

TRIAGE DATA: NON-CBI INVENTORY
(YES)
CAS SR NO
IN TRANSIT

ONGOING REVIEW
YES (DROP/REFER)
NO (CONTINUE)
REFER

SPECIES
Hm N
RBT

TOXICOLOGICAL CONCERN:
LOW
MED
(HIGH)

USE:

PRODUCTION:

COMMENTS

8(E)-12223A

H/H

ACUTE DERMAL TOXICITY IN HUMANS IS OF HIGH CONCERN BASED ON MORTALITY. A 24-YEAR OLD MALE ACCIDENTALLY EXPOSED TO SOLUTION OVER 10% OF SKIN SURFACE DIED 11 HOURS AFTER EXPOSURE DESPITE IMMEDIATE WASHING AND MEDICAL TREATMENT. TOXIC SIGNS INCLUDED VOMITING, AND INCREASED RESPIRATION AND CARDIAC RATES. PATHOLOGY REVEALED CONGESTION AND HEMORRHAGE OF THE HEART, LUNGS, THYMUS, AND LIVER.

ACUTE DERMAL TOXICITY IN RABBITS (SEX, GROUP SIZES, AND DOSE VOLUMES NOT INDICATED) IS OF HIGH CONCERN BASED ON LETHALITY. IN 15-MINUTE EXPOSURES, WITH AS LITTLE AS 3% OF SKIN SURFACE TREATED, 2/2 RABBITS DIED. WITH 1% OF SKIN SURFACE EXPOSED, NO DEATHS OCCURRED. IN ONE MINUTE EXPOSURES, FOLLOWED BY EXTENSIVE WASHING WITH WATER, WITH 10% OF SKIN SURFACE TREATED, 2/2 RABBITS DIED. WITH 5% SKIN SURFACE TREATED, 1/2 RABBITS DIED. WITH 3% SKIN SURFACE TREATED, NO DEATHS OCCURRED. WASHING OF THE SKIN WITH SODIUM BICARBONATE AFTER ONE-MINUTE EXPOSURE AND APPLICATION OF SODIUM BICARBONATE PASTE TO THE TREATED AREA SHOWED NO DIFFERENCE IN MORTALITY FROM WASHING WITH WATER, ALTHOUGH SEVERITY OF SKIN LESIONS APPEARED SLIGHTLY LESS. DEATHS OCCURRED IN 2 TO 5 HOURS WITH FEW SYMPTOMS SHOWING. ANIMALS BECAME LETHARGIC AND COMATOSE BEFORE DEATH. GROSS PATHOLOGY REVEALED THE PERIPHERAL VENOUS SYSTEM WAS DISTENDED AND THE RIGHT VENTRICLE OF THE HEART WAS DEVOID OF BLOOD. MICROSCOPIC EXAMINATION WAS NOT REPORTED.

8E Number and Chemical Name	Rank	Reason or Brief Description
-12355 "Material 4577", proprietary chemical	Low	In 1966 a proprietary chemical of unknown identity proved to be a definite sensitizing agent. Its principal allergenic component was inferred to be Butynediol, 25% aqueous.
-12455 G.A.F. Biopal VRO 20, CAS 11096-42-7	Low	In 1956 the chemical was tested neat and 10% in distilled water for dermatotoxicity and found in both cases to be a primary irritant when covered.
-11612 Epoxide No. 8, CAS 68609-97-2 Cresyl glycidyl ether, CAS 2210-79-9 Butyl glycidyl ether, CAS 2426-08-6 Phenyl glycidyl ether, CAS 122-60-1	Low	The submitter concluded the material was not a dermal sensitizer based on insult patch testing in 1973 with 57 volunteers using 9 patches of 10% in DEHP solution. The test sponsor claimed no reports on reactions in the consuming population from 1967 to 1973.
-12090 Vinyl acetate	Low	The chemical was tested in 1973 for olfactory fatigue in humans in tests designed to generate data suitable for evaluating an odor threshold. The chemical has been extensively studied and is now subject to a workplace standard.
-12223 Monochloroacetic acid, CAS 79-11-8	Low	Duplicate of earlier submission, 8(e) CAP -5933.